

Package leaflet: Information for the user

Omnilax 4 g powder for oral solution in sachet

Macrogol 4000

Read all of this leaflet carefully before you start giving this medicine to your child because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Omnilax is and what it is used for
2. What you need to know before you give Omnilax
3. How to give Omnilax
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1. What Omnilax is and what it is used for

Omnilax contains the active substance macrogol 4000 (polyethylene glycol = PEG) and belongs to a group of medicines called osmotic laxatives. It works by adding water to in the stools which helps to relieve problems caused by very slow bowel movements. Omnilax is not absorbed into the bloodstream or broken down in the body.

Omnilax is used for the treatment of constipation in children from 6 months to 8 years of age. This medicine is a powder that you dissolve in a glass of water and drink. It usually takes 24 to 48 hours to work.

The treatment of constipation with any medicine should only be an addition to a healthy lifestyle and diet.

2. What you need to know before you give Omnilax

Do not give Omnilax:

- if your child is allergic (hypersensitive) to macrogol (polyethylene glycol) or any of the other ingredients of this medicine (listed in section 6).
- if your child has an existing disease, such as, severe intestinal disease:
 - inflammatory bowel disease (such as ulcerative colitis, Crohn's disease, abnormal dilation of the bowel)
 - perforation of the bowel or risk of perforation of the bowel
 - ileus or suspicion of intestinal obstruction
- painful abdominal syndromes of uncertain cause.

Do not give this medicine if any of the above applies to your child. If you are not sure, talk to your pharmacist or doctor before giving the medicine.

Warnings and precautions

Cases of allergic reactions involving rash and swelling of the face or throat (angioedema) have been reported in adults after taking products containing macrogol (polyethylene glycol). Isolated severe cases of severe allergic reactions have been reported causing faintness, collapse or breathing difficulties and feeling generally unwell. If your child experiences any of these symptoms you should seek medical help immediately.

An organic disorder should have been ruled out before initiation of treatment, please talk to your pharmacist or doctor before giving the medicine.

As this medicine can sometimes cause diarrhoea, check with a doctor or pharmacist before giving this medicine if your child:

- has impaired liver or kidney function or
- is taking diuretics (water tablets), as your child may be at risk of low sodium (salt) or potassium levels in the blood.

Before taking Omnilax, talk to your doctor or pharmacist if you know that you have a swallowing disorder.

Avoid mixing Omnilax and starch-based food thickeners if you have difficulties with swallowing. This may result in a watery liquid which could get into your lungs and cause pneumonia if you can't swallow properly.

Other medicines and Omnilax

There is a possibility that the absorption of other medicinal products taken could be transiently reduced during use with Omnilax, particularly medicinal products with a narrow therapeutic index or short half-life such as digoxin, anti-epileptics, coumarins and immunosuppressive agents, leading to decreased efficacy. Tell your doctor or pharmacist if your child is taking, or have recently taken any other medicines, including medicines obtained without a prescription.

If your child has swallowing problems and needs food thickeners to thicken fluids in order to swallow them safely, avoid mixing Omnilax with starch-based food thickeners. Omnilax may counteract the effect of starch-based food thickeners causing preparations that need to remain thick for people with swallowing problems to liquefy.

Pregnancy and breast-feeding

Omnilax can be used during pregnancy and breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

No studies on the effects on the ability to drive and/or use machines have been performed.

Important information about some of the ingredients of Omnilax

Due to the presence of sulphur dioxide, it may rarely cause severe hypersensitivity reactions and breathing difficulties.

This medicine contains 0.28 mg of sorbitol in each sachet.

Omnilax can, however, be used if your child is diabetic or on a galactose-free diet.

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially "sodium-free".

3. How to use Omnilax

Always take Omnilax exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is dependent on your child's age.

- *From 6 months to 1 year:* 1 sachet per day.
- *From 1 to 4 years:* 1-2 sachets per day.
- *From 4 to 8 years:* 2-4 sachets per day.

Dissolve the contents of the sachet in a glass of water (at least 50 mL) immediately before use and give to your child to drink. If only one sachet is needed, give your child the medicine in the morning. If more than one sachet is needed, give half of the dose in the morning and half of the dose in the evening.

In children over one year of age, the daily dose can be adjusted according to the effect obtained.

Please note:

- Omnilax usually takes 24 to 48 hours to work.
- The duration of treatment with Omnilax should not exceed 3 months in children.
- Improvement in the frequency of your child's bowel movements after taking Omnilax can be maintained by keeping to a healthy lifestyle and diet.
- Talk to your pharmacist or doctor if the symptoms worsen or do not improve.

If you give more Omnilax than you should

Giving too much Omnilax may cause diarrhoea, stomach pains or vomiting. The diarrhoea usually disappears when treatment is stopped or the dose reduced.

If your child suffers from severe diarrhoea or vomiting you should contact a doctor as soon as possible as your child may require treatment to prevent loss of salts (electrolytes) from fluid loss.

If you forget to give Omnilax

Give the next dose as soon as you remember but do not give a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Omnilax can cause side effects, although not everybody gets them.

The side effects that are usually mild and do not last long include:

In children:

Common (may affect up to 1 in 10 people):

- Abdominal (belly) pain
- Diarrhoea which may also cause soreness around the back passage (anus)

Uncommon (may affect up to 1 in 100 people):

- Nausea (feeling sick) or vomiting
- Abdominal (belly) bloating

Not known (frequency cannot be estimated from available data):

- Allergic (hypersensitivity) reactions (rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse)

In adults

Uncommon (may affect up to 1 in 100 people):

- Urgent need to go to the toilet
- Faecal incontinence

Not known (frequency cannot be estimated from available data):

- Low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma.
- Dehydration caused by severe diarrhoea especially in the elderly
- Skin redness

Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Omnilax

Keep out of the reach and sight of children.

Do not take Omnilax after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Omnilax does not require any special storage conditions.

Reconstituted solution should be stored well covered in a refrigerator (2°C-8°C) and is stable for 6 hours.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Omnilax contains

- The active substance is macrogol 4000. One sachet contains 4 g macrogol 4000.
- The other excipients are saccharin sodium (E954) and flavour (orange-grapefruit aroma containing maltodextrin, sorbitol (E420), butylhydroxyanisole (E320) and acacia (E414)).

What Omnilax looks like and contents of the pack

Off white powder in a sachet for making up a solution with a taste of orange-grapefruit.

Omnilax is available in pack sizes of 10 sachets, 20 sachets, 30 sachets and 50 sachets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pro Health Pharma Sweden AB
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252 78 Helsingborg, Sweden

Manufacturer

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